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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/714,040	11/15/2000	Paul J. Carter	P0710P1D1	5212

7590 04/20/2005
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EXAMINER

BLANCHARD, DAVID J

ART UNIT PAPER NUMBER

1642

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/714,040

Applicant(s)

CARTER, PAUL J.

Examiner

David J. Blanchard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25, 29 and 38-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25, 29 and 38-41 is/are rejected.
- 7) ☒ Claim(s) 42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-24, 26-28 and 30-37 are cancelled.
Claims 25 and 29 have been amended.
Claims 38-42 have been added.
2. Claims 25, 29 and 38-42 are pending and under examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. This Office Action contains New Grounds of Rejections.

Objections/Rejections Withdrawn

5. The objection to claim 29 as being of improper dependent for failing to further limit the subject matter of a previous claim is withdrawn in view of the amendments to the claim.
6. The rejections of claims 25 and 29 under 35 U.S.C. 112, second paragraph, as being indefinite on various grounds is withdrawn in view of the amendments to claims.
7. The rejection of claim 25 under 35 U.S.C. 102(b) as being anticipated by Rhind S. K. is withdrawn in view of applicant's arguments and the amendments to the claim
8. The rejection of claims 25 and 29 under 103(a) as being unpatentable over Rhind S. K. in view of Cunningham et al is withdrawn in view of applicant's arguments and the amendments to the claims.

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9. The rejection of claims 25 and 29 under 103(a) as being unpatentable over Glennie et al in view of Wahl et al and Cunningham et al is withdrawn in view of applicant's arguments and the amendments to the claims

New Grounds of Rejections

10. Claims 25, 29 and 38-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite for reciting "disulfide Cys-X-X" in claim 25. It is unclear what is contemplated by the term "disulfide Cys-X-X" because the sequence "Cys-X-X" only contains a single cysteine residue or a single thiol-containing residue and would not form a disulfide by itself. The cysteine in the "Cys-X-X" formula is capable of forming a disulfide when paired with another cysteine residue (i.e., with the cysteine in the Cys-X-X of the other Fab), however, it is unclear if the cysteine can form a disulfide in the context of "Cys-X-X", wherein X is Ala, Arg, Pro or Asp as recited.

11. Claims 25, 38 and 40-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Bodmer et al (WO 98/01974, 3/9/1989).

The claims are drawn to a composition comprising a monospecific F(ab)₂ which is free of F(ab)₂ having hinge region intrachain disulfide bonds, free of contaminating arsenite and each Fab of the F(ab)₂ comprises a CH1 domain fused to an amino acid disulfide Cys-X-X, wherein X is Ala, Arg, Pro or Asp and the cysteine forms a disulfide

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bond to form the F(ab)2. Claims 40-41 are drawn to a composition comprising a F(ab)2 wherein each Fab comprises a CH1 region fused to an amino acid sequence Cys-X-X, wherein X is Ala, Arg, Asp or Pro.

Bodmer et al teach F(ab)2 fragments of monoclonal antibodies that comprise a heavy chain CH1 domain fused to the hinge region, which comprises the amino acid sequence Cys-X-X, wherein the Cys-X-X sequence is Cys-Pro-Pro or Cys-Pro-Arg (see entire document, especially pages 2, 5, 8, 10 and Figure 1). "Comprising" is open language and does not exclude additional unrecited elements (MPEP 2111.03). Thus, the CH1 domain fused to a hinge region comprising the amino acid sequence Cys-X-X of Bodmer reads on the claims. Bodmer et al does not teach chemically cross-linking each Fab to produce the F(ab)2 and thus, the F(ab)2 of Bodmer is free of contaminating arsenite. Therefore, it is the Examiners position that the F(ab)2 taught by Bodmer is free of contaminating arsenite.

Therefore, Bodmer et al anticipate the claims.

Conclusion

12. Claim 42 is objected to as being dependent upon a rejected base claim.

13. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Respectfully,
David J. Blanchard
571-272-0827

Jeffrey Siew
JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
4/14/05